

REMARKS

Claims 19-21, 24-27 and 29-32 and 34-42 are pending in the present application. By this Amendment, Claims 27 and 34 are amended; and Claim 33 is canceled. Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following remarks.

I. PRIOR ART REJECTIONS

Claim Rejections Under 35 U.S.C. §103 (a)

Claims 19-21, 24-27 and 29-42 stand rejected under 35 U.S.C. §103 (a) as being unpatentable over European Publication No. 0022377 to Levine (hereafter "Levine") in view of U.S. Patent No. 4,521,520 to Jacke (hereafter "Jacke"). This rejection is respectfully traversed.

Claim 19 provides, *inter alia*, a kit comprising a sample collection device comprising a strip having a handle end and a collection end, said collection end having a collection pad, the collection pad being a sponge-like material made of polyvinyl alcohol, wherein the device includes a means for facilitating removal of at least a portion of the collection pad from the strip to recover the analyte for detection or measurement by laboratory analysis; and an information card for providing information about the patient. Claim 27 provides, *inter alia*, a device for laboratory analysis of an analyte, the device comprising a strip having a handle end and a collection end, the collection end having attached thereon a collection pad for collecting and drying a liquid biological sample containing the analyte, wherein the collection pad consists essentially of a sponge-like material made of polyvinyl alcohol; wherein the device further comprises a means for facilitating removal of at least a portion of the collection pad from the strip to recover the analyte for detection or measurement by laboratory analysis.

Levine provides a device for obtaining stool samples. According to the Examiner, Levine discloses a device for obtaining a biological sample having a handle (4) and a collection end (8) having an opening (6) that may serve to facilitate removing a portion of the absorbent pad containing the sample. There is also an absorbent pad (10) on the collection end of the device. The examiner acknowledges that Levine fails to teach polyvinyl alcohol (PVOH) as the absorbent material for the pad (10).

Jacke provides a method for in house occult blood testing. According to the Examiner, Jacke discloses a device for obtaining a biological sample. The device includes a

handle end having an absorbent pad attached to the collection end, wherein the absorbent pad is PVOH.

It is respectfully submitted that the combination of Levine and Jacke fails to teach or suggest Applicants' claimed invention. Levine fails to teach or suggest Applicants' invention as claimed. Applicants' invention, as claimed, includes means for facilitating removal of at least a portion of the collection pad from the strip. In various embodiments, these means are a hole. Levine fails to teach or suggest these means for facilitating removal of at least a portion of the collection pad from the strip. The Examiner points to element 6 in Levine as teaching a hole. However, element 6 is directed to a hole in the top sheet wherein, once the device is used in a manner akin to toilet paper, this top sheet having hole 6 is removed and disposed of, possibly by placing in the toilet. As such, this hole 6 does not facilitate removal of at least a portion of the collection pad from the strip as there is no teaching or suggestion to remove any portion of the pad from the strip. Rather, once the top sheet is removed, the remainder of the device is folded such that it may be mailed. As such, it would not have been desirable to have a hole that facilitated removal of at least a portion of the collection pad, as the sample on the pad may leak through, creating an unsanitary situation for the postal carrier.

The device in Levine does include a second hole 18 in the device. Again, this hole 18 does not facilitate a removal of at least a portion of the collection pad, but rather permits the pad to remain on the strip while it is tested. Accordingly, as holes 6 and 18 do not facilitate removal of at least a portion of the collection pad, and as there is no teaching or suggestion of any means for facilitating removal of at least a portion of the collection pad, it is respectfully submitted that Levine fails to teach or suggest Applicants' claimed invention.

It is respectfully submitted that Jacke fails to remedy the deficiencies of Levine. As stated by the examiner, Jacke is used to teach the use of PVOH in a material for collecting biological samples. While Applicants respectfully submit that it would not have been obvious to substitute PVOH for the pad material in Levine due to the fact that this would interfere with one of the stated properties of the Levine device (the ability to retain the sample during mailing), it is respectfully submitted that Jacke fails to teach or suggest any means for facilitating removal of at least a portion of the collection pad. As such, Jacke fails to remedy the deficiencies of Levine and, accordingly, it is respectfully submitted that the combination of Levine and Jacke fails to teach or suggest Applicants' claimed invention.

For at least the reasons given above, Applicants respectfully submit that Claims 19 and 27 are allowable over the prior art of record. Furthermore, as Claims 20-21, 24-26, 29-32 and 34-42 recite additional claim features and depend from Claim 19 or Claim 27, these claims are also allowable over the prior art of record.

II. CONCLUSION

For at least the reasons given above, Applicants submit that Claims 19-21, 24-27 and 29-32 and 34-42 define patentable subject matter. Accordingly, Applicants respectfully request allowance of these claims.

The foregoing is submitted as a full and complete Response to the Office Action mailed December 22, 2003, and early and favorable consideration of the claims is requested.

Should the Examiner believe that anything further is necessary in order to place the application in better condition for allowance, the Examiner is respectfully requested to contact Applicants' representative at the telephone number listed below.

A check in the amount of \$420.00 is included for a two-month extension of time. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 50-0951.

Respectfully submitted,

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